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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,428

08/04/2006

Hiroshi Nagai

SHOB-0005 (037498-006)

9228

46188

7590

04/16/2008

THELEN REID BROWN RAYSMAN & STEINER LLP

P. O. BOX 640640

SAN JOSE, CA 95164-0640

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,428	Applicant(s) NAGAI ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1,2 and 4-7 are pending in the application. Claim 3 was cancelled in the amendment filed 1/8/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 1/8/08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1,2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000-60427A abstract in view of Iwasaki et al. (US 7,014,876B2) and JP 2001-253879 abstract as stated 10/4/07.

4. Applicant asserts that JP 2000-60427A discloses that black tea comprising epicatechin gallate, epigallocatechin, epigallocatechin gallate and epicatechin at a total of at least twice that of ordinary black tea is effective in maintaining hepatic function health and that catechins (such as that presently claimed) are equal in terms of their activity towards maintaining healthy hepatic function and that regardless of the types of

catechins, these catechins are effective in maintaining hepatic function health when contained in an amount at least twice that contained in ordinary black tea.

5. Applicant asserts that the reference of JP 2000-60427A does not disclose that a beverage containing catechins as presently claimed in an amount of 1mg to 30 mg per 100 ml are effective in suppressing arteriosclerosis and obesity caused by neutral fat deposition as well as allergic symptoms, with the exclusion of hepatic disorders.

6. The reference of JP 2000-60427A was not used to teach of the amount of catechin (such as that presently claimed) but that the use of catechins found in black tea (i.e. a health drink) are used to improve the function of the liver.

The reference of Iwasaki et al. (US 7,014,876B2) teaches that the catechins found in Oolong tea (black tea) is used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20). Therefore it would be obvious to one ordinarily skilled in the art to try/utilize catechins found in black tea in a health drink, such as one to improve the function of the liver. The disclosures of JP 2000-60427A and Iwasaki et al. (US 7,014,876B2) are drawn to the same utility, such as a health drink containing black tea and therefore the results for varying the amount of catechin would be predictable and lead to improving the function of the liver. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation.”

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. Applicant asserts that the reference of JP 2001-253879 does not disclose that a beverage containing catechins as presently claimed in an amount of 1mg to 30 mg per 100 ml is effective in suppressing both allergic symptoms and hyperlipemia.

8. JP 2001-253879 discloses that catechins as presently claimed have antiallergic actions and in combination with the disclosures above it would be obvious to optimize the amount of catechin utilized in a health drink capable of improving the function of the liver, will also inherently have antiallergic actions and capable of suppressing hyperlipemia.

9. Applicant asserts that JP 2000-60427A and JP 2001-253879 do not disclose that in a composition comprising the catechin presently claimed, the catechin of the present invention has an amount range that enables the simultaneous suppression of entirely different diseases, namely, allergic symptoms and hyperlipemia represented by arteriosclerosis, obesity and so on, with the exclusion of hepatic disorders.

10. JP 2001-253879 discloses that catechins as presently claimed have antiallergic actions and in combination with the disclosures above it would be obvious to optimize the amount of catechin utilized in a health drink capable of improving the function of the liver, will also inherently have antiallergic actions and be capable of suppressing hyperlipemia.

11. It is respectfully pointed out that instant claim 2 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process,

determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

No claims are allowed at this time.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.


Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/588,428	NAGAI ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	